''(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(D); or

''(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect on the date of enactment of this Act, including with respect to applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are approved or pending on that date.

SEC. 12. STUDY CONCERNING RESEARCH INVOLVING CHILDREN.

(a) CONTRACT WITH INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for—

(1) the conduct, in accordance with subsection (b), of a review of—

(A) Federal regulations in effect on the date of the enactment of this Act relating to research involving children;

(B) federally prepared or supported reports relating to research involving children; and

(C) federally supported evidence-based research involving children; and

(2) the submission to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, not later than 2 years after the date of enactment of this Act, of a report concerning the review conducted under paragraph (1) that includes recommendations on best practices relating to research involving children.

(b) AREAS OF REVIEW.—In conducting the review under subsection (a)(1), the Institute of Medicine shall consider the following:

(1) The written and oral process of obtaining and defining ''assent'', ''permission'' and ''informed consent'' with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Federal Regulations).

(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child's research involvement, particularly in terms of research versus therapeutic treatment.

(3) The definition of ''minimal risk'' with respect to a healthy child or a child with an illness.

(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.

(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

(c) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children.

SEC. 13. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.

Section 499 of the Public Health Service Act (42 U.S.C. 290b) is amended—

(1) in subsection (b), by inserting ''(including collection of funds and awarding of grants for pediatric research and studies on drugs)'' after ''mission'';

(2) in subsection (c)(1)—

(A) by redesignating subparagraph (C) as subparagraph (D); and

(B) by inserting after subparagraph (B) the following:

''(C) A program to collect funds and award grants for pediatric research and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)).'';

(3) in subsection (d)—

(A) in paragraph (1)—

(i) in subparagraph (B)—

(I) in clause (ii), by striking ''and'' at the end;

(II) in clause (iii), by striking the period and inserting ''; and''; and

(III) by adding at the end the following:

''(iv) the Commissioner of Food and Drugs.''; and

(ii) by striking subparagraph (C) and inserting the following:

''(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—

''(i) representatives of the general biomedical field;

''(ii) representatives of experts in pediatric medicine and research;

''(iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and

''(iv) representatives of the general public, which may include representatives of affected industries.''; and

(B) in paragraph (2), by realigning the margin of subparagraph (B) to align with subparagraph (A);

(4) in subsection (k)(9)—

(A) by striking ''The Foundation'' and inserting the following:

''(A) IN GENERAL.—The Foundation''; and

(B) by adding at the end the following:

''(B) GIFTS, GRANTS, AND OTHER DONATIONS.—

''(i) IN GENERAL.—Gifts, grants, and other donations to the Foundation may be designated for pediatric research and studies on drugs, and funds so designated shall be used solely for grants for research and studies under subsection (c)(1)(C). Other gifts, grants, or donations received by the Foundation may also be used to support such pediatric research and studies.

''(ii) REPORT.—The recipient of a grant for research and studies shall agree to provide the Director of the National Institutes of Health and the Commissioner of Food and Drugs, at the conclusion of the research and studies—

''(I) a report describing the results of the research and studies; and

''(II) all data generated in connection with the research and studies.

''(iii) ACTION BY THE COMMISSIONER OF FOOD AND DRUGS.—The Commissioner of Food and Drugs shall take appropriate action in response to a report received under clause (ii) in accordance with section 409I(c)(7), including negotiating with the holders of approved applications for the drugs studied for any labeling changes that the Commissioner determines to be appropriate and requests the holders to make.

''(C) APPLICABILITY.—Subparagraph (A) does not apply to the program described in subsection (c)(1)(C).'';

(5) by redesignating subsections (f) through (m) as subsections (e) through (l), respectively;

(6) in subsection (h)(11) (as so redesignated), by striking ''solicit'' and inserting ''solicit,''; and

(7) in paragraphs (1) and (2) of subsection (j) (as so redesignated), by striking ''(including those developed under subsection (d)(2)(B)(i)(II))'' each place it appears.

SEC. 14. PEDIATRIC ADVISORY COMMITTEE.

(a) IN GENERAL.—The Secretary of Health and Human Services shall, under section 222 of the Public Health Service Act (42 U.S.C. 217a), convene and consult an advisory committee on pediatrics (referred to in this section as the ''advisory committee'').

(b) PURPOSE.—

(1) IN GENERAL.—The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs and in consultation with the Director of the National Institute of Health, on all matters relating to pediatrics, including pediatric therapeutics.

(2) MATTERS INCLUDED.—The matters referred to in paragraph (1) include—

(A) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, and 505A of the Federal Food, Drug, and Cosmetic Act;

(B) identification of pediatric research priorities and the need for additional treatments of specific pediatric diseases or conditions; and

(C) the ethics, design, and analysis of pediatric clinical trials.

(c) COMPOSITION.—The advisory committee shall include representatives of pediatric health organizations, pediatric researchers, relevant patient and patient-family organizations, and other experts selected by the Secretary.

(d) CLARIFICATION OF AUTHORITIES.—

(1) IN GENERAL.—The Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (referred to in this subsection as the ''Subcommittee''), in carrying out the mission of reviewing and evaluating the data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers, shall—

(A) evaluate and, to the extent practicable, prioritize new and emerging therapeutic alternatives available to treat pediatric cancer;

(B) provide recommendations and guidance to help ensure that children with cancer have timely access to the most promising new cancer therapies; and

(C) advise on ways to improve consistency in the availability of new therapeutic agents.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Secretary shall appoint at least 13 voting members to the Pediatric Subcommittee.

(B) REQUEST FOR PARTICIPATION.—The Subcommittee shall request participation of the following members in the scientific and ethical consideration of topics of pediatric cancer, as necessary:

(i) At least 2 pediatric oncology specialists from the National Cancer Institute.

(ii) At least 6 pediatric oncology specialists from—

(I) the Children's Oncology Group;

(II) other pediatric experts with an established history of conducting clinical trials in children; or

(III) consortia sponsored by the National Cancer Institute, such as the Pediatric Brain